

Appl. No.: 10/709,194  
Arndt dated 11/12/2004  
Reply to Office Action of 11/02/2004

**Listing of Claims:**

**Claim 1** (Previously presented) A method for extracorporeal collection of blood components from a donor/patient comprising:

removing blood from a donor/patient through a single needle;  
flowing said blood into a dual stage blood processing vessel;  
separating plasma from said blood within said blood processing vessel;  
collecting at least a portion of said plasma in a plasma collection reservoir separate from said blood processing vessel;  
separating red blood cells from said blood within said dual stage blood processing vessel;  
collecting at least a portion of said separated red blood cells in a red blood cell collection reservoir separate from said blood processing vessel, wherein said plasma separation and collection steps are completed at least partially contemporaneously with said red blood cell separation and collection steps;  
returning uncollected blood components of said blood to said donor/patient through said single needle; and  
replacing fluid volume in said donor/patient by flowing a replacement fluid to said donor/patient through said single needle.

**Claim 2** (Previously presented) A method as recited in Claim 1, whereby the red blood cell collecting step provides for obtaining a double volume of collected red blood cells.

**Claim 3** (Previously presented) A method as recited in Claim 2 in which said double volume of collected red blood cells totals substantially about 400 milliliters contained in two substantially separate reservoirs.

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**Claim 4** (Previously presented) A method as recited in Claim 1, wherein said plasma collection step is completed at least partially separately from said red blood cell collection step.

**Claim 5** (Previously presented) A method as recited in Claim 1, wherein prior to said red blood cell collection step, and separate from said plasma collection step, said method further comprises a red blood cell collection set-up phase including:

establishing a hematocrit of at least about 80 within said separated red blood cells within said blood processing vessel and an AC ratio within said blood at about 8.

**Claim 6** (Previously presented) A method as recited in Claim 5, further comprising maintaining said hematocrit and AC ratio during said red blood cell separation and collection steps.

**Claim 7** (Previously presented) A method as recited in Claim 1 in which said step of delivering a replacement fluid includes flowing replacement fluid at a rate equal to the total flow rate of collected blood components multiplied by the desired fluid balance percentage resulting within the donor/patient.

**Claim 8** (Previously presented) A method as recited in Claim 7 in which said step of delivering a replacement fluid includes pumping replacement fluid at a rate equal to the total flow rate of collected fluids minus the inlet flow rate of anticoagulant multiplied by the desired fluid balance percentage resulting within the donor/patient.

**Claim 9** (Previously presented) A method as recited in Claim 7 in which a replacement fluid is pumped from a source first to an intermediate reservoir prior to ultimate delivery to the donor/patient.

**Claim 10** (Previously presented) A method as recited in Claim 7 in which a replacement fluid is delivered to the donor/patient in a bolus.

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**Claim 11** (Previously presented) A method as recited in Claim 7 in which a replacement fluid is delivered to the donor/patient in a substantially continuous fashion.

**Claim 12** (Previously presented) A method as recited in Claim 1 further comprising:  
retaining the separated red blood cells in a first stage of the processing vessel;  
establishing a pre-determined packing factor for the separated red blood cells within said blood processing vessel;  
and flowing the red blood cells to red blood cell outlet.

**Claim 13** (Previously presented) A method as recited in Claim 12 in which said collecting step further includes a step for collecting at least a portion of the separated plasma in a plasma collection reservoir separate from said blood processing vessel to establish collected plasma; and wherein said plasma collection step is performed at least partially contemporaneously with said red blood cell collection step.

**Claim 14** (Previously presented) A method as recited in Claim 13, wherein said plasma collection step is performed prior to said red blood cell collection step.

**Claim 15** (Previously presented) A method as recited in Claim 13, wherein said plasma collection step is performed at least partially after said red blood cell collection step.

**Claim 16** (Previously presented) A method as recited in Claim 13, wherein said red blood cell collection step is performed at least partially after said plasma collection step.

**Claim 17** (Previously presented) A method as recited in Claim 11 further comprising establishing a packing factor of at least about 13 for the separated red blood cells within said blood processing vessel.

**Claim 18** (Previously presented) A method as recited in claim 17 wherein said packing factor is between 11 and 21.

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**Claim 19** (Previously presented) A method as recited in claim 18 wherein said packing factor is at least about 13.

**Claim 20** (Previously presented) A method as recited in Claim 19 in which the packing factor is about 16.

**Claim 21** (Previously presented) A method as recited in Claim 17 which further includes establishing an AC ratio in the blood processing vessel of between about 6 and about 16.

**Claim 22** (Previously presented) A method as recited in Claim 17 in which the packing factor is about 16 during the contemporaneous collection of separated plasma and separated red blood cells and the packing factor is then reduced to about 13 during the at least partial step of collecting separated red blood cells after the performance of the collection of separated plasma.

**Claim 23** (Previously presented) A method as recited in Claim 1, further comprising a set up step prior to said collecting steps; said set up step comprising:

flowing the separated blood components out of said blood processing vessel, wherein substantially all of said separated blood components flowing out of the blood processing vessel are accumulated for re-infusion to a donor/patient during the set-up step.

**Claim 24** (Previously presented) A method as recited in Claim 23, wherein said blood is flowed into said blood processing vessel at an inlet flow rate, and said set-up step comprises:

reducing said inlet flow rate.

**Claim 25** (Previously presented) A method as recited in Claim 23, wherein said blood processing vessel is rotated at an rpm rate, and wherein said set-up step comprises:

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increasing said rpm rate.

**Claim 26** (Previously presented) A method as recited in Claim 1, whercin said processing vessel includes a first stage and a second stage, the second stage being separated from said first stage by a dam, a blood inlet for communicating blood into the first stage, a plasma outlet disposed in the second stage and a red blood cell outlet disposed in the first stage; and wherein during said plasma collection step, said method further comprises:

separating plasma from said blood within said centrifugal dual stage blood processing vessel to establish separated plasma, whereby a portion of the separated plasma flows over the dam in the processing vessel to the plasma outlet in the second stage of the processing vessel;

separating red blood cells from said blood within said centrifugal dual stage blood processing vessel to establish separated red blood cells whereby the separated red blood cells remain in the first stage of the processing vessel and flow to the red blood cell outlet; and

recirculating a portion of the uncollected separated blood components into said blood processing vessel.

**Claim 27** (Previously presented) A device for extracorporeal separation and collection of blood components from a donor/patient, comprising:

a centrifugal blood processing channel into which blood from a donor/patient is adapted to be flowed, and in which said blood is separated into at least separated plasma and separated red blood cells; said centrifugal dual stage blood processing channel including a first stage and a second stage, the second stage being separated from said first stage by a dam, a blood inlet for communicating blood into the first stage, a plasma outlet disposed in the second stage and a red blood cell outlet disposed in the first stage; said centrifugal blood processing channel being adapted to be used with:

a removable plasma collection reservoir operably connected to said centrifugal blood processing channel, whereby into which at least a portion of said separated plasma is collected;

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a removable red blood cell collection reservoir operably connected to said blood processing channel whereby a portion of said separated red blood cells are collected in said red blood cell collection reservoir; and

a replacement fluid assembly which is operably connectable to the donor/patient; wherein said replacement fluid assembly is adapted to deliver replacement fluid to the donor/patient.

**Claim 28** (Previously presented) A disposable blood tubing set adapted to be used with a device for extracorporeal separation and collection of blood components from a donor/patient, said disposable blood tubing set comprising:

a disposable centrifugal dual stage blood processing vessel into which blood from a donor/patient is adapted to be flowed, and in which said blood is separated into at least separated plasma and separated red blood cells; said centrifugal dual stage blood processing vessel including a first stage and a second stage, the second stage being separated from said first stage by a dam, a blood inlet for communicating blood into the first stage, a plasma outlet disposed in the second stage and a red blood cell outlet disposed in the first stage;

a plasma collection reservoir operably connected to said centrifugal blood processing vessel, whereby into which said plasma collection reservoir at least a portion of said separated plasma is collected;

a red blood cell collection reservoir operably connected to said blood processing vessel whereby a portion of said separated red blood cells are collected in said red blood cell collection reservoir; and

a disposable fluid flow cassette assembly operably interconnected to said centrifugal blood processing vessel, said cassette assembly having an intermediate reservoir disposed therein, said intermediate reservoir being adapted to receive separated uncollected blood components from said centrifugal blood processing vessel; and

a replacement fluid assembly which is operably connected to said fluid flow cassette and said intermediate reservoir; wherein said replacement fluid assembly is adapted to deliver replacement fluid to said intermediate reservoir for subsequent infusion of the replacement fluid into a donor/patient.